

**STATEMENT OF PAMELA MARRS  
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BEFORE THE  
HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON  
OVERSIGHT AND INVESTIGATIONS  
HEARING ON  
MEDICAID PRESCRIPTION DRUG REIMBURSEMENT  
DECEMBER 7, 2004**

Good morning, Mr. Chairman and distinguished members of this Committee.

Thank you for the opportunity to appear before you today. For the past 15 years, I have been the Chief Financial Officer of DEY, L.P. Founded in 1978 and located in Napa, California, DEY is a specialty pharmaceutical company focused on the development, manufacturing and marketing of prescription drug products for the treatment of respiratory diseases and respiratory-related allergies. In addition to our facility in Napa, we also have a distribution center in Allen, Texas.

Last year Congress and the Administration took important steps to reform and improve Medicare reimbursement policy when it passed the Medicare Modernization Act.

As you know, the system of reimbursement using a percentage of average wholesale price, or AWP, badly needed to be reformed and many in the pharmaceutical industry, including DEY, supported reform.

Medicaid reimbursement has typically had a spread between the cost of the drug paid by the provider and the reimbursement amount. That spread goes to the provider, not the manufacturer. Until the mid 1990's, my understanding is that it was not unusual for sales people, when speaking to customers, to compare their spreads with those of their competitors. Beginning in the late 1990's, as a result of litigation, government investigations and the OIG Compliance Program Guidance for Pharmaceutical Manufacturing issued in 2003, my understanding is that the industry has become sensitive to this practice and it has largely stopped.

At DEY, we have developed and implemented a major compliance program over the last few years designed to ensure that our sales force is compliant with the OIG Guidance.

We have also seen many changes on the government side that are reducing the emphasis on AWP. Last year's Medicare law will, by 2006, virtually eliminate AWP as a basis for Medicare reimbursement under Part B. The new Medicare Part D drug benefit will not use AWP as a basis for government payment for drugs. So, both by industry practice and government action, the situation is changing.

**Is the spread still meaningful to providers?**

Yes, because they often depend on the spread to cover their costs of dispensing, which often exceed the small dispensing fees they receive from Medicaid.

**How does DEY set AWP for generics?**

At DEY, our historical practice for generic drugs has been to set the generic AWP as a percentage off of the brand's AWP when the product is launched. Usually that percent has been about 10%. After that, our practice has been not to change AWP on generics.

**Why doesn't DEY lower its AWP on generic drugs?**

The simple answer is that, given the system that now exists, our customers won't buy from us if we lower our AWP. This was confirmed about a year and a half ago when a reporting service lowered their published AWP for our drugs without consulting us. Our customers told us they would stop buying from us with the lower AWP. This could have put many of our employees out of work overnight. So we went to court and the court issued a temporary restraining order stopping the service's action.

### **Why do we need an AWP at all?**

At this point, the current system is based on AWP and customers rely on it and won't buy a product without it. As evidence of this, about two years ago, because of the litigation, we tried to market a new drug with no AWP. Our customers said they wouldn't buy it so we set an AWP which happened to be lower than those of our competitors. As a direct result of the lower AWP, we sold almost nothing of a drug for which we had projected to have sales of \$6 million. These experiences taught us that reimbursement reform has to come from the government and be applied to the whole industry. If a generic company – especially a small one like ours – tries to buck the AWP system on its own, it can be forced out of whole business lines.

### **Do our profits on generic drugs increase as the spread increases?**

In DEY's case, the answer is no.

First, it is important to keep in mind that the drug manufacturers don't get the money which comes from the spread. Money realized from the spread goes to the providers.

Second, in the case of generic drugs, a larger spread actually means a lower profit margin for the manufacturer. Because generic drugs are a commodity, price competition is fierce. If the spread for a particular generic DEY drug is getting larger, it is almost always because the AWP of the drug is remaining the same, while the actual selling price is getting lower. At the same time, our costs are increasing and our margins are declining.

This situation is shown dramatically in the case of albuterol, which has been repeatedly cited in CMS reports as having some of the largest spreads of any drug.

For the last ten years, the spread on albuterol, which is one of DEY's biggest generic products in terms of volume sold, has been getting larger and larger as the price drops

because of competition. Have our profits increased as the spread has grown? No. At the current time, we are close to breakeven on albuterol due to continuing erosion of the market price.

**Why doesn't the industry get together and agree on a solution to the AWP problem?**

It is not within the purview of the industry to make such a change. We at DEY are anxious to provide information and assistance so we can help the government bodies that will effect such changes. We have provided written comments on multiple occasions to CMS as that body has worked toward reform of the current AWP-based system in an effort to assist with this process.

As I said at the outset, I am the Chief Financial Officer of DEY. I've held that position since 1989. Most of the documents I was asked about in my staff interview or afterwards came out of the sales and marketing department and, with some exceptions where I was copied or was the addressee, I saw them for the first time during the litigation.

Having said that, I hasten to add that I have learned a lot about AWP and these documents from the litigation and I'll try to be as helpful as I can in answering your questions about them.

Thank you for your time. I would be pleased to answer any questions you may have.